August 18, 2000

Comments of Environmental Defense on the Petroleum Coke Test Plan and Robust Summary under the High Production Volume Chemical Initiative

Environmental Defense is a national non-profit environmental advocacy organization with approximately 300,000 members dedicated to the protection of human health and the environment by, inter alia, assuring that adequate toxicity data on widely used chemicals exist and are publicly available. Environmental Defense, together with the Environmental Protection Agency and the Chemical Manufacturers Association, jointly developed the framework for the High Production Volume Chemical initiative. We appreciate this opportunity to comment on the petroleum coke test plan and robust summary, as downloaded from http://www.epa.gov/chemrtk/viewsrch.htm.

The submission by the American Petroleum Institute was well written and organized, so the document was quite reviewable. There are a number of issues that are raised by the document regarding the toxicological and human health sections. These comments do not address the sections on ecological effects and environmental fate.

- 1) We agree that no additional acute toxicity testing in animals is needed. Based on the available information on inhalation and dermal exposures coupled with the cytotoxicity data presented in the section on genetic toxicity, additional acute toxicity tests would be of little or no value.
- 2) We agree that no further in vitro or in vivo genetic tests are needed.
- 3) We agree that reproductive and developmental toxicity studies should be conducted on green coke via inhalation exposures for the reasons outlined in the document.
- 4) The presentation of information on repeat 'dose' and cancer studies is puzzling. It appears that a 2-year repeat dose study on green coke was conducted via the inhalation route in rats and monkeys, vet no cancer data were presented. Are cancer data available for this study? The results of these studies indicate an increase in lung weights. This finding coupled with the knowledge that vanadium pentoxide and nickel are lung carcinogens raises significant concern. Specifically, the table on page 5 indicates that substantial amounts of vanadium are present in both green coke and anode-grade calcined coke (120-400 ppm). Likewise, high amounts of nickel are present in anode-grade calcined coke. Both of these metals are toxic and nickel compounds are considered likely human carcinogens (see IARC monographs and NTP's Report on Carcinogens for summaries). NTP will report on the carcinogenicity of vanadium pentoxide in 2001. The dermal cancer studies presented in the robust summaries are inadequate to address this issue, and in particular are inadequate to address cancer risks arising from inhalation exposure to green coke. Based on the available information, we must disagree with the American Petroleum Institute's assertion that no further repeat dose testing is needed.

We appreciate this opportunity to comment.

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